

**Clinical Laboratory Program**

99 Chauncy Street, 2<sup>nd</sup> Floor, Boston, MA 02111  
(617) 753-8439/8438 (617) 753-8240 - Fax

TO: Requesters of Clinical Laboratory Improvement Amendment [CLIA] Application

On February 28, 1992, the Department of Health and Human Services published regulations in the **Federal Register** implementing the **Clinical Laboratory Improvement Amendments of 1988 (CLIA)**. This material was rewritten due to publication of CMS- 2226-F: 42 CFR 493 Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule on January 24, 2003, with an effective date of April 24, 2003. **CLIA requires every individual and facility testing human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements.** In addition, the CLIA legislation requires financing of all regulatory costs, e.g., applications, inspections, certificates, through fees assessed to laboratories. CLIA applies to any individual or facility performing any clinical diagnostic patient testing as outlined above, regardless of whether a fee for service is charged.

To register in the CLIA program, laboratories must first register by completing an application [CMS-116 form]. This form collects information about your laboratory's operation and is necessary to assess fees, to establish baseline data and to fulfill statutory requirements of the Public Health Service Act. This information will provide the laboratory surveyor an overview of your laboratory's operation if it is subject to an onsite survey. When completing this form, the information submitted should be based on your laboratory's operation (hours of operation, number of personnel involved in testing) as of the date the form is completed. **Note that the CLIA identification number should be left blank as this will be assigned when the application form is processed.**

Upon completion and submission of the CMS-116 form, a fee remittance coupon will be issued to you indicating your CLIA identification number, the amount due for the certificate and, if applicable, the compliance fee. The appropriate certificate (certificate of waiver, certificate for provider-performed microscopy procedures, or registration certificate) will be issued upon receipt of payment.

Once completed, the forms [application and test list] should be returned to the State Agency at the following address:

DIVISION OF HEALTH CARE QUALITY  
CLINICAL LABORATORY PROGRAM  
99 CHAUNCY STREET, 2<sup>ND</sup> FLOOR  
BOSTON, MA 02111

If you need additional information concerning CLIA, or if you have questions about these forms, call (617) 753-8439/8438 or write to the address indicated above.

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**CLIA Application**

**REQUIRED DOCUMENTS**

- ☐ Application for Clinical Laboratory Improvement Amendments of 1998 [CLIA] Certificate - complete, sign, date and return

download CMS 116 form from website: <http://www.cms.hhs.gov/forms/>

- ☐ List of Laboratory Tests Performed On-Site - complete and return  
download from website

Failure to provide this information in a timely manner will result in a delay in the processing of information required for the issuance of a CLIA certificate.

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Visit the Centers for Medicare and Medicaid Services [CMS] CLIA homepage to learn more about the CLIA program. The regulations, interpretative guidelines, test complexity information, list of approved Proficiency Testing programs, list of approved accreditation agencies, etc. may be found on this homepage.

CLIA homepage: <http://www.cms.hhs.gov/clia/>